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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,198	07/19/2000	Hai Yan	MBHB00-422	2259

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/619,198	YAN ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,12,13,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,12,13,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/19/04 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicants' arguments filed 8/19/04 have been fully considered but they are not deemed to be persuasive.

4. The amendment filed 8/19/04 overcomes the objection under 35 U.S.C. 132 to the 4/24/04 new matter amendment to the specification.

5. Claims 6-9,12-13 & new claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention, for the reasons similarly made of record in Paper No: 17 (mailed 8/21/03) & 20040217, and as follows.

Applicants argue on pages 6-8 of the response that "'non-VGF protein' is not a negative limitation intended to exclude the larger VGF polypeptide described by Salton et al., because by definition a VGF fusion protein excludes the Salton VGF protein", and argues that the term "fusion" is defined by the Oxford Dictionary of Biochemistry and Molecular Biology. This is an incorrect assumption because:

1) no where in the specification is the term "**non**-VGF protein" contemplated; thereby, constituting new matter for this broader concept, versus the specific and narrower examples described on pages 19-21 of the specification, and

2) as previously made of record, Applicants' specification itself alternatively defines that "[t]he term 'VGF fusion polypeptide' refers to a fusion of *one or more amino acids* (***such as*** a heterologous peptide or polypeptide)... [emphasis added]", which clearly does not exclude the "*fusion of one or more amino acids*" present in Salton's VGF protein to the *"amino or carboxyl-terminus of [the] VGF polypeptide"* of SEQ ID NO:7 [emphasis added], because such is an open-ended definition, and because the protein of SEQ ID NO: 7 and Salton's protein are different proteins, as illustrated by their different sizes and their different amino acid sequences (page 19, lines 11-13). *In arguendo*, Salton teach a rat VGF fusion protein comprising the human VGF polypeptide of SEQ ID NO: 7, which is "produced...naturally" (i.e., consistent with the Oxford Dictionary of Biochemistry and Molecular Biology's definition for "fusion protein"). Alternatively, recombinantly produced proteins do not materially change the fusion protein produced (i.e., a product-by-process limitation). Accordingly, the courts have held that if the

product (i.e., fusion proteins) in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe,* 227 USPQ 964, 966 (Fed. Cir. 1985): *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

Additionally, and in contrast to Applicants' assertions on page 7 of the response, page 9 of the specification does include "orthologs" in the definition of fusion polypeptides, as Applicants correctly recite on page 7 of the response. Thus, Applicants' arguments are inconsistent with the definition the specification itself gives for fusion polypeptides, which takes precedence.

It is again noted that Applicants can obviate this rejection by actually claiming that described within the specification (i.e., as it relates to a fusion polypeptide consisting of the amino acid sequence SEQ ID NO: 7 fused to an amino acid sequence that aids in the detection of the fusion polypeptide, etc.) versus that currently claimed (i.e., as it relates to "a **non**-VGF protein"). Thus, Applicants' arguments remain not persuasive for the reasons extensively made of record, and because a few specific disclosed examples do not constitute the generic concept of "a **non**-VGF protein", in contrast to Applicants' assertions; thereby, still constituting new matter.

As previously made of record, *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention* [emphasis added]", which Applicants clearly have not conveyed, and which the specification itself does not support.

6. Claims 6-9, 12-13 & 22-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reason made of record in Paper No: 17 (mailed 8/21/03) & 20040217.

As previously made of record, the issue remains that Applicants have chosen to claim the invention after-the-fact by excluding that taught by Salton et al (1991). In contrast, the courts have held that negative limitations that exclude compounds do not meet the requirements of 35 U.S.C. 112 because it attempts to claim the invention by excluding what was not invented rather than what was invented. *In re Schechter, 205 F2d 185, 98 USPQ 144 (CCPA 1953).* Thus, Applicants' arguments are not persuasive.

In summary, no **generic** "amino acid sequences from a ***non-VGF*** protein" are described within the instant specification. Thus, one of ordinary skill in the art could not reasonably visualize what constitutes such widely-variable sequences that make up such generic "fusion polypeptides"; thereby, not meeting the written description requirements under 35 U.S.C. 112, first paragraph, for the reasons extensively made of record. See MPEP 2163.

It is noted that Applicants have chosen to ignore the Examiner's suggestions for obviating this rejection.

7. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fusion polypeptides containing reasonably well known polypeptide

sequences that possess the properties recited in claim 22, does not reasonably provide enablement for fusion polypeptides that contain structurally and functionally unknown and uncharacterized amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification merely lists the uses recited in claim 23 (a)-(d) in the paragraph bridging pages 19 & 20 of the specification. In contrast, no guidance on how to use such fusion polypeptides is explained within the specification. Neither are any examples provided within the instant specification on how such putative fusion proteins can be made with a definable purpose (i.e., including the loosely listed "therapeutic implications" listed in Table III). Therefore, because the metes and bounds such addition protein sequences constitute are unknown, one skilled in the art would not know how to make and use the invention, as currently claimed, without requiring undue experimentation to determine such after-the-fact, if later discovered.

8. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, it is unknown what metes and bounds the recitation "has a therapeutic activity different from... VGF" entails, because no disease state to be treated nor any definable therapeutic activity" is recited in the claim; thereby, also being incomplete.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
October 19, 2004

ROBERT C. HAYES, PH.D
PATENT EXAMINER